DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

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Certifier R. LEDESMA

Food and Drug Administration

21 CFR Part 170

[Docket No. 01N–0234]

Food Additives: Food Contact Substance Notification System

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is requesting input on whether the agency should establish regulations permitting the licensing of the rights to manufacture and market a food contact substance for the use that is the subject of an effective food contact notification (FCN). FDA is requesting this input in response to a comment on a proposed rule published in the **Federal Register** of July 13, 2000. The action requested in the comment concerning the transfer of rights granted under the FCN process is beyond the scope of the July 2000 proposal, and FDA is publishing this document so that interested persons may have adequate time to consider and comment on this issue.

DATES: Submit written or electronic comments by [*insert date 75 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Mitchell Cheeseman, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–418–3083.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Modernization Act of 1997 (Public Law 105–115) established a premarket notification process for food contact substances (FCSs). The FCN process began to operate on October 22, 1999, and is now the primary method for authorizing new uses of food additives that are FCSs. In the **Federal Register** of July 13, 2000 (65 FR 43269), the agency proposed regulations to facilitate implementation of the notification process. FDA provided 75 days for comment on the proposed rule. FDA received three comments from trade associations representing the food packaging industry. One comment requested that FDA issue regulations to permit the transfer of rights granted under the FCN process. Because that request is outside the scope of the proposed rule, in this advanced notice of proposed rulemaking, FDA is soliciting input from interested parties on the action requested by that comment. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule responding to the remaining comments on the proposal and codifying the proposed regulations with limited changes.

II. The American Plastics Council Comment

The comment on the proposed rule received from the American Plastics Council (APC) requests that FDA issue regulations to permit a manufacturer identified in an effective FCN to transfer by sale, licensing, or otherwise to another manufacturer the right to manufacture and market the FCS for the use that is the subject of the FCN, provided that FDA is advised of the transfer. The APC comment argues that such a process would maintain the safety of the FCS because the FCS would continue to be manufactured in the manner reviewed by FDA and would still be authorized only for the use that was the subject of the original FCN. As noted, FDA believes that the issue raised in the APC comment is outside the scope of the proposed rule, and thus, the agency has not addressed the APC comment in the final rule published elsewhere in this issue of the **Federal Register**. To assist the agency in determining what, if any, action it should take, FDA is requesting comments from interested parties on whether the agency should permit a

manufacturer to transfer the rights, granted by an effective FCN, to manufacture and market an FCS.

III. FDA's Current Practice

Under section 409(h)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(h)(2)(C)), a notification is only effective for the FCS identified in the FCN and not for a similar or identical FCS manufactured or prepared by another manufacturer. Currently, FDA requires any subsequent manufacturer who wishes to market an FCS for a use that is the subject of an effective FCN to submit a new notification to FDA. In addition, the manufacturer identified in an effective FCN may authorize other manufacturers to reference information contained in the effective FCN. Thus, other manufacturers may have to provide only limited additional information in subsequent FCNs but they must separately notify FDA and wait 120 days for their FCN to become effective. One effect of FDA issuing the regulations requested in the APC comment would be that subsequent manufacturers could more rapidly market FCSs.

IV. Paperwork Reduction Act of 1995

This advanced notice of proposed rulemaking contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Analysis of Impacts

Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act of 1995 require cost-benefit and other economic analyses of regulatory alternatives. FDA requests comments on economic issues associated with regulations permitting a manufacturer or supplier identified in an effective FCN to transfer by sale, licensing, or otherwise to another manufacturer or supplier the right to manufacture or market the FCS for the use that is the subject of the FCN. The agency particularly requests answers or comments on the following questions:

1. What paperwork and other costs will you incur in submitting a transfer application?

2. What health and safety safeguards operate under transfer?

3. Will consumers benefit from establishing such a transfer right? If so, how?

4. What effect would transfer have on the costs and market position of small businesses?

5. How many transfers do you anticipate issuing for each new FCN?

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment from the American Plastics Council submitted to FDA Docket No. 99N–5556, dated September 26, 2000.

VIII. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this notice by [*insert date 75 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 9/28/01

September 28, 2001.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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